

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Sep 2026

A clinical trial to comparison the effectiveness of skeletal and dental of palatal expansion after miniscrew-assisted fixed with conventional method in patients who need orthodontic treatment and palatal expansion

Protocol summary

Summary

Objective: To comparison the effectiveness of skeletal and dental of palatal expansion after miniscrew-assisted fixed with conventional method in patients who need orthodontic treatment and palatal expansion. Design: A single-blind block randomized clinical trial. Study population: Patients who need orthodontic treatment and palatal expansion are refereeing to Dental Clinic of Mashhad Faculty of Dentistry. Inclusion criteria: who need to maxillary arches expand; aged between 12 and 16 years; who show pre-puberty stage (before CS3) based on cervical vertebral stadium (CVS). Exclusion criteria: In maturity or later of CS3 stages; having certain systemic diseases; using medications that impact on orthopedic and orthodontic response; who patients need to using other appliance (face mask, etc.) simultaneously with expansion appliance. Sample size: 74 cases. Study intervention: The control group are revising conventional appliance Hyrax based on dental and intervention group are revising miniscrew-assisted fixed for palatal expansion. Study outcome: Evaluation and comparison the effectiveness of skeletal and dental including rate of disruption hyoid, rate of tipping crown, gingival recession, fenestration/dehiscence with cone beam computed tomography (CBCT) and root recession with appliance expansion in intervention and control groups 4 months after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017022632787N1**

Registration date: **2017-03-01, 1395/12/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-03-01, 1395/12/11

Registrant information

Name

Farzane Lale Alizade

Name of organization / entity

Mashhad Faculty of Dentistry

Country

Iran (Islamic Republic of)

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+98 51 3841 3007

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to comparison the effectiveness of skeletal and dental of palatal expansion after miniscrew-assisted fixed with conventional method in patients who need orthodontic treatment and palatal expansion

Public title

The effectiveness of skeletal and dental of palatal expansion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: who need to maxillary arches expand; aged between 12 and 16 years; who show pre-puberty stage (before CS3) based on cervical vertebral stadium (CVS). Exclusion criteria: In maturity or later of CS3 stages; having certain systemic diseases; using medications that impact on orthopedic and orthodontic response; who patients need to using other appliance (face mask, etc.) simultaneously with expansion appliance.

Age

From **12 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Postal code

Approval date

2015-09-06, 1394/06/15

Ethics committee reference number

IR.mums.sd.REC.1394.55

Health conditions studied

1

Description of health condition studied

Orthodontic treatment and palatal expansion

ICD-10 code

Z51.8

ICD-10 code description

Other specified medical care

Primary outcomes

1

Description

The effectiveness of skeletal and dental including rate of disruption hyoid, rate of tipping crown, gingival recession, fenestration/dehiscence

Timepoint

4 months after intervention

Method of measurement

Cone beam computed tomography (CBCT)

Secondary outcomes

1

Description

Root recession

Timepoint

4 months after intervention

Method of measurement

Appliance expansion

Intervention groups

1

Description

Control group: Who are revising conventional appliance Hyrax based on dental for palatal expansion, the effectiveness of skeletal and dental are examining 4 months after intervention.

Category

Other

2

Description

Intervention group: Who are revising miniscrew-assisted fixed for palatal expansion, the effectiveness of skeletal and dental are examining 4 months after intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Mashhad Faculty of Dentistry Dental Clinic
Full name of responsible person
Farzane Lale Alizade
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Mashhad University of
Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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Vice Chancellor for Research, Mashhad University of
Medical Sciences, Ghoreishi building, Daneshgah
Street
City
Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research, Mashhad University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

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empty
Analytic Code
empty

Data Dictionary
empty